UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,)))
v.) Criminal No: 09-CR-10330-GAO
 STRYKER BIOTECH, LLC, MARK PHILIP, WILLIAM HEPPNER, DAVID ARD and JEFFREY WHITAKER, 	ORAL ARGUMENT REQUESTED ORAL ORAL ARGUMENT REQUESTED
Defendants.))

DEFENDANTS' MOTION TO EXCLUDE TESTIMONY OF GOVERNMENT WITNESS DR. LARRY DEUTSCH, AND MEMORANDUM IN SUPPORT THEREOF

Defendants hereby move to exclude the testimony of Government witness Dr. Larry

Deutsch, currently scheduled to testify for the prosecution on Wednesday, January 18, on

grounds that such testimony is not relevant to the charges in this matter and would serve only to

mislead and confuse the jury.

Dr. Deutsch testified before the grand jury in this case on November 6, 2008. He has not been interviewed by the Government either before or since appearing before the grand jury. In the course of his 29 minutes of grand jury testimony, Dr. Deutsch made clear that:

- He has not used OP-1 *since 2005*, prior to the start of the conspiracy alleged by the Government.
- He was first introduced to OP-1 as part of a hospital research study, and not as a result of any "sales pitch" by any Stryker Biotech employee.
- He could recall no specific conversation with any alleged conspirator or unindicted alleged co-conspirator about the OP-1 or Calstrux products.

In light of this information, Dr. Deutsch cannot possibly provide any evidence that would assist the jury in deciding the ultimate question raised by this Indictment—whether the Defendants defrauded surgeons during the period of the conspiracy.

Dr. Deutsch also testified that he had a single patient treated with OP-1 that experienced excessive post-operative drainage, but drainage that Dr. Deutsch admitted "was a kind of bacteria that's usually a contaminant, not a true infection." Grand Jury Tr. of Larry Deutsch (Nov. 6, 2008) (hereafter, "Deutsch Tr.") at 10:9-10. The Government has conceded that it cannot prove causation of any "adverse event" related to the use of OP-1 and Calstrux, including the potential adverse event experienced by Dr. Deutsch's patient. Importantly, the Government has also recently conceded to the Court that the relevance of adverse event evidence is because "adverse events are notice to the company," not because the details of any specific adverse event are relevant to the felony fraud charges in the Superseding Indictment. Tr. of Final Pretrial Status Conference (Jan. 4, 2012), at 48. To that end, Dr. Deutsch could not recall having any specific conversation with any Stryker Biotech employee notifying the company of this adverse event, and he only had a vague and unreliable recollection of having provided any notice at all. See Deutsch Tr. at 14:12-18.

Dr. Deutsch has no evidence to offer of <u>any</u> conduct by the Defendants during the alleged conspiracy period, and any testimony he could provide about "notice" to Stryker Biotech regarding any particular adverse event occurring in his surgeries is unreliable at best. Certainly, testimony about the details of any adverse event experienced by Dr. Deutsch are irrelevant to whether notice of that adverse event was provided to Stryker Biotech, and should be excluded as

both irrelevant and unduly prejudicial. This promises to be a lengthy trial, with over 60 potential Government witnesses. Dr. Deutsch's testimony is not relevant and should be excluded.¹

BACKGROUND

1. <u>Dr. Deutsch Did Not Use OP-1 During the Alleged Conspiracy Period, and Never Interacted With Any Co-Conspirator</u>

As a review of his grand jury transcript makes clear, Dr. Deutsch first became exposed to OP-1 Implant while working at Cooper University Hospital in New Jersey, "as part of an FDAapproved study" in tibial fractures. Deutsch Tr. at 6:10-12. He further testified that "he [didn't] remember how he first heard about" OP-1 Putty; although he believed that "Stryker representatives" came to his office to discuss OP-1 Putty, he could not remember those representatives' names. Id. at 8:3-18. During his course of Dr. Deutsch's testimony, only two Stryker employees were mentioned. First, the prosecutor twice tried to prompt Dr. Deutsch's memory in the grand jury about whether he interacted with unindicted co-conspirator Peter Murphy, and each time Dr. Deutsch testified that he had no memory of meeting Mr. Murphy. Id. at 8:19-21, 12:3-4. Second, Dr. Deutsch said that he may have discussed OP-1 with a Stryker representative named "Matt Slater or something like that. I'm really not sure." *Id.* at 11:22-23. Mr. Slater is not an alleged unindicted conspirator in this case. Most importantly, Dr. Deutsch testified that he "ha[sn't] used OP-1 since 2005." Id. at 13:19. Given that Dr. Deutsch did not use either the Calstrux or OP-1 products during the period of the alleged conspiracy, and given that he cannot recall a single conversation with any member of the alleged conspiracy, any testimony that Dr. Deutsch might offer about his interactions with Stryker Biotech simply is not relevant to the charges at hand, and should be excluded.

¹ To the extent that the Government contemplates eliciting expert testimony from Dr. Deutsch, that testimony should be excluded on the independent ground that Defendants have never received any expert disclosure from the Government for him.

2. <u>Dr. Deutsch Should be Excluded From Testifying About Potential "Adverse Events"</u>

Dr. Deutsch could not recall in how many patients he had used the combination of OP-1 and Calstrux. He "remember[ed] [he] did a few cases, and [he] thought there was excessive drainage associated with that." Deutsch Tr. at 9:12-14. In preparation for his grand jury testimony, Dr. Deutsch contacted Stryker Biotech, who provided him a list of three patients in which he used the combination, and one additional patient for whom Dr. Deutsch served as assistant surgeon. *See id.* at 19:4-24. Dr. Deutsch testified, after reviewing the records for the three patients for whom he served as primary surgeon, that:

And, you know, one patient did fairly well. The other patient didn't do well; seemed to have a lot of inflammation around the nerve, some local swelling. The third patient drained an excessive amount with what was actually a fairly tiny procedure. And it almost seemed like it was an allergic reaction. We ended up taking her back, washing her out, and culturing. And it did grow out a bacteria, but it was a kind of bacteria that's usually a contaminant, not a true infection.

Id. at 10:2-10.

In response to later questioning by the Government about "problems," "infections," and "drainage" he experienced with the OP-1/Calstrux combination, Dr. Deutsch testified that his "problems" were limited to "just the one patient that I took back, [D.R.]":

And I just, I felt like this was some sort of inflammatory reaction to the OP-1, and that the drainage was excessive, and it didn't really look like an infection, and she didn't act like an infection. And my partners actually, you know, chastised me, saying that, you know, I'm too reactive; that, you know, this was not scientific; you can't react to the one procedure.

Id. at 13:1-7.

While Dr. Deutsch testified that he notified Stryker Biotech about this potential adverse event, he did not "really recall" to whom he spoke: "[I]t's a long time ago, and I don't remember

exactly who we actually [talked] to about this." *Id.* at 14:12-17. Although the Government has listed several exhibits that might serve to establish that notice of this event was indeed provided to Stryker Biotech by Dr. Deutsch, none of those exhibits could be authenticated or introduced through Dr. Deutsch himself, since he is not copied on these internal Stryker Biotech communications.² Dr. Deutsch's testimony about any notice provided to Stryker Biotech would be unreliable, unfairly prejudicial, and cumulative. Therefore, any testimony by Dr. Deutsch about the nature of the adverse event experienced by patient D.R., or about "notice" he may have provided to Stryker Biotech of that event, also should be excluded.

CONCLUSION

For the reasons stated above, Defendants request that the Court exclude any testimony by Dr. Larry Deutsch.

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(d), Defendants respectfully request oral argument on this motion.

² If such exhibits are admissible, they could only properly be admitted through other witnesses on the Government's witness list.

Respectfully submitted,

STRYKER BIOTECH, LLC

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January 16, 2012

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LOCAL RULE 7.1(a)(2) CERTIFICATION

I, Robert L. Ullmann, hereby certify pursuant to Local Rule 7.1(a)(2) that, on January 16, 2012, counsel for the Defendants conferred in good faith with the counsel for the Government, but were not able to resolve or narrow the issues raised by the above motion.

/s/ Robert L. Ullmann Robert L. Ullmann

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and that paper copies will be sent to any indicated as non-registered participants, on January 16, 2012.

January 16, 2012

/s/Robert L. Ullmann Robert L. Ullmann